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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,893	09/28/2001	Alessandra D'Azzo	SJ-01-0020	4347

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ST. JUDE CHILDREN'S RESEARCH HOSPITAL
OFFICE OF TECHNOLOGY LICENSING
332 N. LAUDERDALE
MEMPHIS, TN 38105

EXAMINER
FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/966,893	D'Azzo et al.
Examiner	**Art Unit**
Christian L. Fronda	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above, claim(s) 1-7 and 14-20 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 8-13 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on Sep 28, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
4) ☐ Interview Summary (PTO-413) Paper No(s).
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other

DETAILED ACTION

Election/Restriction

1. Applicants' election with traverse of Group III, claims 8-13, Galactosialidosis, and protective protein/cathepsin A (PPCA) in Paper No. 5 is acknowledged. The traversal is on the grounds that the methods and compositions of Groups I-IV are generic to the production of proteins and that they are related as composition and method of making said composition. Furthermore, Applicants' position is that examination of each of the disease-enzyme combination is unwarranted and would be a significant hardship since to would require separate examination of at least over 100 claim groups. This is not found persuasive for the reasons stated in the Office Action dated 02/04/2003 (Paper No. 4): the processes of Groups I, II, IV, VI, and VIII are distinct both physically and functionally, require different process steps, reagents, and parameters, and have different purposes; each of the products of III, V, and VII are independent chemical entities and require different literature searches; and each of the processes of Groups I, II, IV, VI, and VIII do not require the products of Groups III, V, and VII. Each of the diseases and enzymes or proteins are patentably distinct and independent with different etiologies. A search of all the inventions in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches that have different limits, boundaries, scope, and subject matter. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent subject matter, restriction for examination purposes is proper.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8-13, Galactosialidosis, and protective protein/cathepsin A (PPCA) are under consideration in this Office Action.

Claim Objections

3. Claims 9 and 10 are objected to because they non-elected subject matter. Applicants are required to cancel the claims or amend the claims to recite the elected subject matter of protective protein/cathepsin A (PPCA) and Galactosialidosis.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 8-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to any polypeptide of any structure and function to be used in a composition for treating any lysosomal storage disorder wherein the claimed polypeptide is selectively imported into macrophages. The specification, however, only provides a single representative protein encompassed by these claims: protective protein/cathepsin A (PPCA) in a composition for treating Galactosialidosis. There is no disclosure of any particular structure to function/activity relationship in the single PPCA to any other protein of any structure and function for treating any lysosomal storage disorder. The specification fails to provide a written description of any polypeptide of any structure and function to be used in a composition for treating any lysosomal storage disorder wherein the claimed polypeptide is selectively imported into macrophages. Thus, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

6. Claim 8-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any pharmaceutical composition comprising any polypeptide of any structure and function to be used for treating any lysosomal storage disorder wherein the claimed polypeptide is selectively imported into macrophages. The specification provides guidance and examples for injecting a baculovirus expressed and purified

neuraminidase and PPCA into PPCA deficient mice resulting in increased activities of cathepsin A and neuraminidase. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding whether any pharmaceutical composition comprising any polypeptide of any structure and function can be used to treat any patient having any lysosomal storage disorder without harming the patient is lacking. Furthermore, knowledge regarding whether any baculovirus expressed and purified neuraminidase and PPCA used to treat PPCA deficient mice can be used to treat any patient having Galactosialidosis without harming the patient is lacking. Thus, searching for any pharmaceutical composition comprising any polypeptide of any structure and function or any baculovirus expressed and purified neuraminidase and PPCA used to treat PPCA deficient mice which can be used to treat any patient having any lysosomal storage disorder without harming the patient is well outside the realm of routine experimentation and predictability in the art of success in determining whether the patient can be treated without any harm is extremely low.

The amount of experimentation to search for any pharmaceutical composition comprising any polypeptide of any structure and function which can be used to treat any patient having any lysosomal storage disorder without harming the patient is enormous and entails searching for any protein of any structure and function and determining whether any pharmaceutical composition comprising the protein or baculovirus expressed and purified neuraminidase and PPCA used to treat PPCA deficient mice would be useful in treating the patient having any lysosomal storage disorder such as Galactosialidosis without harming the patient.

Since such experimentation is not routine in the art where the expectation of obtaining any pharmaceutical composition comprising any polypeptide of any structure and function which can be used to treat any patient having any lysosomal storage disorder is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the a specific composition which is effective in treating a patient having Galactosialidosis. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 8-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Sharp (WO 00/39150). The claims are product-by-process claims which are not limited by the manipulations of the recited steps. No patentable weight is give to the process where the claimed protein is produced in an insect cell culture (see MPEP § 2113). For examination purposes, the claims will only be examined as being directed to a pharmaceutical composition comprising a polypeptide useful for treating a lysosomal storage disorder.

Sharp teaches TANGO 176 nucleic acids and polypeptides encoded which are useful for treating Galactosialidosis wherein the encoded polypeptide is PPCA and pharmaceutical compositions comprising the TANGO 176 polypeptides (see entire publication especially pp. 27-28 and 65-76). Thus, the reference teachings anticipate the claimed invention.

Conclusion

9. No claim is allowed

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF